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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,866	04/11/2005	John-Olov Jansson	JANSSON7	2241

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BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

LUKTON, DAVID

ART UNIT PAPER NUMBER

1654

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/530,866

Applicant(s)

JANSSON, JOHN-OLOV

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10,14,15,18,20,22,27,28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10,14,15,18,20,22,27,28 and 30 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Pursuant to preliminary amendment (filed 4/11/05) claims 1-10, 14, 15, 18, 20, 22, 27, 28 & 30 have been amended, and claims 11-13, 16, 17, 19, 21, 23-26, 29, 31-37 cancelled. Claims 1-10, 14, 15, 18, 20, 22, 27, 28 & 30 are now pending. (Subsequently, the paper filed 5/1/06 corrected a minor informality in claims 7 and 9).



A restriction is imposed as set forth below. First, however, the following subgenera are defined:

**G1:** a method for treating and/or preventing loss of body weight and body fat in a gastrectomized individual;

**G2:** a method for preventing or treating cachexia in a gastrectomized individual;

**G3:** a method for stimulating appetite and/or stimulating food intake in a gastrectomized individual;

**G4:** a method for stimulating weight gain and/or increasing body fat mass in a gastrectomized individual;

. . . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I ) Claims 1-10, 14, 15, drawn to a method of using a peptide to accomplish one or more of G1 – G4.

II ) Claims 18 and 20, drawn to drawn to a method of using a peptide to accomplish one or more of G1 – G4, and additionally administering a second agent.

The claimed inventions are distinct.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because. The ghrelin peptides can be used without the secondary agents. However, in the event that Group I is elected, and claims therein found allowable, it is likely that Group II will be novel (subject to the same limitations as have been introduced into the Group I method).

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group I is chosen for initial examination, election of each of the following

is required:

- a ) one of the following: (i) in the elected method, one and only one of G1-G4 is required; (ii) in the elected method, two of G1-G4 is required; (iii) in the elected method, three of G1-G4 is required; (iv) in the elected method, all four of G1-G4 is required;
- b ) a specific and fully defined peptide to be used in the elected method;
- c ) one of the following: (i) a peptide *per se* is administered, or (ii) a composition that comprises a peptide is administered;
- d ) in the event that a composition comprising a peptide is administered, election is required of a specific composition, with all components accounted for;
- e ) the route of administration (e.g., oral, subcutaneous, intravenous).

. . . .

In the event that Group II is chosen for initial examination, election of the following is required:

- a ) one of the following: (i) in the elected method, one and only one of G1-G4 is required; (ii) in the elected method, two of G1-G4 is required; (iii) in the elected method, three of G1-G4 is required; (iv) in the elected method, all four of G1-G4 is required;
- b ) a specific and fully defined peptide to be used in the elected method;
- c ) one of the following: (i) a peptide *per se* is administered, or (ii) a composition that comprises a peptide is administered;
- d ) in the event that a composition comprising a peptide is administered, election is required of a specific composition, with all components accounted for;
- e ) the route of administration (e.g., oral, subcutaneous, intravenous);
- f ) a specific "stomach derived factor" or a specific body weight inducing factor.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read 'D. Lukton', is positioned above the printed name.

DAVID LUKTON, PH.D.  
PRIMARY EXAMINER